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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,405

01/06/2005

Li-Hai Katz

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

07/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,405	Applicant(s) KATZ, LI-HAI	
	Examiner JAMES H. ALSTRUM ACEVEDO	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 28-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/6/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/31/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-48 are pending. Claims 1-27 are under consideration in the instant office action. Receipt and consideration of Applicant's IDS (submitted 7/31/06) claims, and remarks/arguments submitted 3/25/08 are acknowledged.

Election/Restrictions

Claims 28-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/25/2008.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 10 are vague and indefinite, because the phrase reading, “chosen from the group comprising, but not limited to” does not clearly set forth the metes and bounds of the group being described. Applicant is encouraged to utilize proper Markush group language (see MPEP 2111.02 and 2173.05(h)).

The term "large" in claim 19 is a relative term which renders the claim indefinite. The term "large" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term large renders the term “acoustically active particles” indefinite.

Claim 1 recites the limitation "the direction of a friction layer" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the direction of flow" in line 4. There is insufficient antecedent basis for this limitation in the claim.

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Claim 1 recites the limitation "the motion" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the efficiency" in line 24. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the diffusion" in line 24. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the interior" in line 25. There is insufficient antecedent basis for this limitation in the claim.

Claims 2-9 recite the limitation "the acoustic radiation force for pushing" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claims 2-9 depend from claim 1, which only recites an asymmetric acoustic radiation force; thus, it is unclear whether the acoustic radiation force for pushing is a different force or the same as the asymmetric acoustic radiation force.

Claim 18 recites the limitation "the carotid artery" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

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Claim 20 recites the limitation "the size" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 20 and 25 recite the limitation "the pores" in line 1 of both claims. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the openings" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "the acoustic pressure" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 recites the limitation "the pore size" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "the dimensions" in line 25. There is insufficient antecedent basis for this limitation in the claim.

Claims 21 and 24 recite the limitation "said pores" in line 4 and 5, respectively. There is insufficient antecedent basis for this limitation in the claim.

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Claim 22 recites the limitation "the side" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "the ultrasonic force" in line 6. There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-8, 13-14, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milo (WO 01/41655), as evidenced by the definition of a bubble, and in view of Trinh et al. (U.S. Patent No. 4,398,925).

Applicant Claims

Applicant claims a method of neutralizing (i.e. dissolving, breaking, or shrinking) acoustically active particles immersed in a flowing fluid in which (a) ultrasonic waves are provided and either (i) push particles in the direction of a friction layer near surface or surfaces or (ii) pushing particles against the fluid flow to stop the particles and hold the particles in place against the surface or surfaces and (b) an acoustic radiation force is provided for neutralizing said ultrasonically active particles.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Milo teaches a device and method of concentrating microbubbles in a tube or vessel through **the generation of ultrasonic waves by a transducer**, which cause **the bubbles (i.e. acoustically active particles) to concentrate (i.e. bubbles are "pushed") at the center of the flowing stream** and are subsequently efficiently removed via a downstream vent tube (title; abstract; pg. 3, lines 15-25; pg. 8, lines 28-31; Figures 3, 4, and 5). Milo teaches that since 1973 it has been known that one could use ultrasonic waves to trap small bubbles in a flowing liquid, such as blood, against the wall of a tube (paragraph bridging pages 1-2). In some embodiments the method can be utilized to treat a patient undergoing heart surgery to remove microbubbles and microparticles from the blood of the patient **by focusing ultrasonic waves into the left ventricle and/or ascending aorta** (i.e. a vessel within the human body) (pg. 5, lines 11-21). The transducer may preferably be in the form of multiple piezo crystals arranged in an annular array located exterior of the aorta (i.e. the vessel does not have an open view). Suitable signals from the transducer suitable for providing high and/or low frequency ultrasonic waves may be

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transmitted simultaneously by activation of a pulse generator (pg. 9, lines 15-20 and line 31 through page 10, line 13). The same crystals can be used **to alternatively produce two different frequencies**. Bubble removal may be monitored by a Doppler sensor, which is well known in the art (pg. 10, lines 25-28). Multiple transducers (e.g. piezoelectric elements) connected via cables to a pulse generator in a control box may be utilized and these may be embedded in a collar that is placed around the neck prior to open-heart surgery (pg. 14, lines 1-8, 11-12, 17-21). Optionally as a backup, an additional collar may be placed downstream from the great origins, namely **where the carotid arteries split prior to entering the skull** (pg. 15, lines 10-14). Milo teaches that bubbles may be directed to an optional needle vent piercing the aorta (pg. 11, lines 12-17; Figures 3 and 4). A vent is necessarily an “open” system, and thus this reads on a vessel open to view. It is noted that bubbles are defined as a thin film of liquid filled with air or gas (see Answers.com bubble definition, accessed July 21, 2008 at <http://www.answers.com/bubble>). Thus, a bubble necessarily reads on encapsulated gas or air.

Trinh teaches an acoustic bubble removal method, wherein **larger bubbles are moved with acoustic energy resonant** with a bath against a well, where the bubbles coalesce and are **subsequently shrunk, broken up, and dissolved into the liquid (i.e. absorption into the liquid)**, which reads on neutralizing bubbles (i.e. acoustically active particles) (title; abstract; col. 1, lines 49-64). Trinh teaches that multiple acoustic modes may be utilized to better control the movement of the bubbles and **smaller bubbles with a size of 50 microns to 1000 microns may be dissolved using frequency sweeps in the range of about 0.5 kHz to 40 kHz** (col. 2, line 52 through col. 3, line 5 and col. 4, lines 22-48).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Milo lacks the teaching of the application of an acoustic force to neutralize acoustically active particles. This deficiency is cured by the teachings of Trinh, which was provided as a secondary reference to demonstrate that the art recognized methods of neutralizing acoustically active particles.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to combine the teachings of Milo and Trinh, because both references are in the same field of endeavor and address the same problem of removing bubbles (i.e. acoustically active particles) from a liquid. An ordinary skilled artisan cognizant of the teachings of Milo would recognize the desirability of removing acoustically active particles from a liquid (e.g. blood) in a medical setting, because the presence of bubbles in physiological fluids poses a serious health risk to patients. An ordinary skilled artisan practicing the methods of Milo to remove bubbles from blood and cognizant of the teachings of Trinh, would be motivated to utilize Trinh's teachings concerning the shrinking, breaking up, and dissolution of bubbles to ensure said bubbles do not pass into the carotid artery and pose a health risk to a patient by entering the circulatory system surrounding the great organs (e.g. brain). Regarding the limitation that the acoustic pushing force and the acoustic neutralizing force are directed against the direction of flow of the fluid, this would have been prima facie obvious per the teachings of Milo, wherein the fluid is blood passing through the aorta towards the carotid arteries, because the criticality of preventing bubbles from passing through the carotid artery and

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reaching the brain is well-known in the art (see Milo: pg. 15, lines 10-26). Regarding the use of different sources to provide the acoustic pushing and acoustic neutralizing forces, this would have been *prima facie* obvious per Milo's suggestion of utilizing multiple transducers and Trinh suggestion to apply various acoustic modes. The term "acoustic mode" is understood to refer to the application of a particular waveform/frequency combination. Regarding the use of the same source to provide the acoustic pushing and acoustic neutralizing forces, this is considered to fall within the skill of the ordinary artisan and the transducer technology available at the time of Applicants' invention, as evidenced by Trinh's description of "sweeping" over a frequency range of 0.5 kHz to 40 kHz to dissolve, break-up, and shrink bubbles (col. 4, lines 22-48). An ordinary skilled artisan would have had a reasonable expectation of success because the movement of bubbles in a fluid through the application of acoustic energy has been known since 1973 (see Milo: pg. 1, line 26 through pg. 2, line 21) and is further described by Milo; and because the ultrasonic frequencies necessary to shrink, break-up, and effectively dissolve bubbles are also well known, as taught by Trinh. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Conclusion

Claims 1-27 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571)

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272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
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